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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,859	09/12/2003	Jong-Soo Woo	DE-1508	8650
1109	7590	07/27/2006	EXAMINER	
ANDERSON, KILL & OLICK, P.C. 1251 AVENUE OF THE AMERICAS NEW YORK,, NY 10020-1182			CLAYTOR, DEIRDRE RENEE	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/660,859

**Applicant(s)**

WOO ET AL.

**Examiner**

Renee Claytor

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's election of Group I **without** traverse is hereby acknowledged. The species election is hereby withdrawn and the entire group is being searched herewith. Claims 1-9 are being examined on the merits herein and claims 10-13 are withdrawn from consideration, as they don't read on the elected group. The election requirement is deemed proper and made FINAL.

### ***Priority***

This application does not claim priority to any prior documents.

### ***Objections***

Claims 6-9 objected to because of the following informalities: missing period at the end of the sentence.

Claim 5 objected to because of the following informalities: missing colons separating itraconazole, acidifying agent, amphiphilic additive, surfactant, and oil.

Appropriate correction to the above is required.

### **Claim Rejections - 35 USC § 102**

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 6, and 7 rejected under 35 U.S.C. 102(b) as being anticipated by Baert et al. (WO 97/44014).

Baert et al. teach a pharmaceutical composition comprising of itraconazole, an amphiphilic additive (e.g., propylene glycol), a surfactant (e.g., hydroxymethylcellulose (HPMC) and an oil (e.g., hydrogenated vegetable oil; Pg. 12, lines 25-37 – Pg. 13, lines 1-4). Baert also teaches that itraconazole comprises the free base form and pharmaceutically acceptable addition salts formed by reaction with appropriate acids such as hydrochloric acid and phosphoric acid (Pg. 1, lines 34-38 – Pg. 2, lines 1-4).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Baert et al. (WO 97/44014) in view of Patel et al. (U.S. Patent #6,248,363).

Baert et al. teach a pharmaceutical composition as discussed above. Baert teach that the composition discussed above can be administered in tablet form for immediate release of itraconazole when orally administered (encompassing claim 4; Pg. 10, lines 23-29) and at any time of the day independently of when food is taken in (encompassing claim 2; Pg. 3, lines 9-13), so that the bioavailability of the drug in fasted and fed states is comparable (Pg. 3, lines 33-34). Such a teaching renders the bioavailability ratio before and after food ingestion at 0.8 or higher (of claim 2) obvious because the comparable bioavailability in fasted and fed states can be construed as a ratio of 1:1.

Baert et al. does not teach the viscosity of the composition or the ratios of each component comprising the composition, and tocopherol as an oil used in the composition.

Patel et al. teach additives such as tocopherol and silica that can be used in a similar composition (Col. 39, lines 11-30). Because of the teachings of Patel that tocopherol and silica can be used as additives in a similar composition, it would have been obvious to use tocopherol in the present composition because Baert et al. teach the use of silica in their composition (Pg. 12, lines 25-38 – Pg. 13, lines 1-4) and both compounds are additives according to Patel.

Furthermore, it is obvious to vary and/or optimize the amount of itraconazole provided in the composition, according to the guidance provided by Baert et al., to provide a composition having the desired properties such as the desired viscosity, desired ratios of itraconazole and acidifying agent, amphiphilic, surfactant and oil. It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Baert et al., which teaches a pharmaceutical composition comprising itraconazole, an acidifying agent (e.g. hydrochloric or phosphoric acid), an amphiphilic additive (e.g. propylene glycol), a surfactant and an oil (e.g., hydrogenated vegetable oil), and also a dosage form in which the bioavailability of itraconazole in the fasted and fed state in a mammal is

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comparable, with the teachings of Patel et al. who teach that an additive such as tocopherol can be used in such a composition. It would have been further obvious to vary and/or optimize the amount of itraconazole to achieve the desired viscosity and ratios of itraconazole to other ingredients in the composition. Accordingly, on having ordinary skill in the art at the time the invention was made would have been motivated to utilize the composition of Baert et al. and utilize tocopherol as an additive of Patel et al. and adjust the ratios of itraconazole, acidifying agent, amphiphilic additive, surfactant, and oil in an effort to obtain a more viscous composition with an increased bioavailability.


### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER